MAY 0 3 2002

K012113

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Date: February 1, 2002

807.92(a)(2)

Trade Name:	Indwelling Fecal Management System (IFMS)
Common Name:	Rectal Irrigation tube
Classification Name(s):	Tubes, Gastrointestinal
Classification Number:	78KNT

807.92(a)(3)

Predicate Device(s)

HDC	Colo-Vage System	K841289
Leon's Fecal Sanitary Tube Manufacture	Leon's Fecal Sanitary Tube	K813526
Bard	Virden Rectal Catheter	Exempt per 21CFR 876.5980 (barium enema retention catheter)

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

807.92(a)(5)

Intended Use(s)

The Indwelling Fecal Management System (IFMS) is indicated for diversion of fecal matter to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enemas/medications.

510(k) Summary
Indwelling Fecal Management System (IFMS)
Bowel Management Systems, LLC

Comparison Chart for Substantial Equivalence

Function	Device Feature			
	IFMS Catheter (Zassi Medical Evolutions) **This submission**	**Colo-Vage System (HDC Corporation)** **K841289**	**Virden Rectal Catheter (Bard)** **Exempt per 21CFR876.5980 (barium enema retention catheter)**	**Fecal Sanitary Tube (Leon's Fecal Sanitary Tube)** **K813526**
Indications for Use	Diversion of fecal matter to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enema/medications.	Colonic irrigation and drainage of fecal matter.	Administration of barium during radiopaque evaluation.	Collection of fecal excretion
Bowel Retention	External Balloon	External Balloon	External Balloon	External Ring
Bowel Irrigation	Silicone lumen with flared, capped port termination	Silicone lumen with flared termination	No irrigation	No irrigation
Drainage Flow Suspension[1]	Intraluminal (ARV) balloon	No drainage suspension	No drainage suspension	No drainage suspension
Anti-Internal Migration	External silicone retention faceplate w/ anchor tabs	No anti-internal migration	No anti-internal migration	No anti-internal migration
Flush / Stool Sampling	Mid-line silicone access port compatible with catheter tip syringe	No flush / stool sampling	No flush / stool sampling	No flush / stool sampling

	IFMS Catheter (Zassi Medical Evolutions) **This submission**	**Colo-Vage System (HDC Corporation)** **K841289**	**Virden Rectal Catheter (Bard)**	**Fecal Sanitary Tube (Leon's Fecal Sanitary Tube)** **K813526**
Enema / Medication Administration	Silicone lumen with flared, capped port termination	Silicone lumen with flared termination	Natural rubber latex lumen with flared termination	No enema / medication administration
Drainage / Collection	Waste collection bag not provided in kit	Sterile drainage unit not provided	No drainage / collection	Waste collection bag integral to the device
Port Access	Sampling / fluid administration	Sampling / fluid administration	Not specified	Not specified
Sterile	Yes	Yes	No	Yes

Footnotes: [1]Allows for temporary closure of catheter drainage lumen during periods of bowel irrigation or for retention of enema/medications after administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 3 2002

Bowel Management Systems, LLC
c/o Ms. Colleen J. Densmore
Official Correspondent
The Anson Group, LLC
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K012113
Trade/Device Name: Indwelling Fecal Management System (IFMS)
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: February 1, 2002
Received: February 4, 2002

Dear Ms. Densmore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012113

Device Name: Indwelling Fecal Management System (IFMS)

Indications For Use: Diversion of fecal matter to minimize external contact with the patient, to facilitate the collection of fecal matter for patients requiring stool management, and to provide access for colonic irrigation to trigger a defecatory response, and administration of enemas/medications.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012113

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)